SUPPORTING STATEMENT FOR
QUALITY MAMMOGRAPHY STANDARDS
LAY SUMMARIES FOR PATIENTS.
0910-0426

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

FDA is seeking OMB clearance of the information collection requirements in 21 CFR 900.12(c)(2). This regulation merely implements a statutory information collection requirement; there is no aditional burden attributable to the regulation.

900.12(c)(2) - Third Party Disclosure (Tab A)

Each mammography facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are "Suspicious" or "Highly suggestive of malignancy," the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

The Mammography Quality Standards Act (the MQSA) (Pub. L. 102-539) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that, to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, shall be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). To become accredited and certified, a facility had to meet national quality standards to be established by the Secretary. The authority to establish these standards, to approve accreditation bodies, and to certify facilities was delegated by the

Secretary to FDA.

Facilities were initially accredited and certified if they met the standards contained within the interim rules issued by FDA in the **Federal Register** of December 21, 1993 (58 FR 67335 and 58 FR 67565) (Tab B) and amended by another interim rule published in the **Federal Register** on September 30, 1994 (59 FR 49808) (Tab C.). More comprehensive standards were proposed by FDA in the **Federal Register** of April 3, 1996 (61 FR 14856, 61 FR 14870, 61 FR 14884, 61 FR 14898, and 61 FR 14908). After some revision in response to the approximately 8000 comments received on the proposed rule, a final rule was published in the **Federal Register** of October 28, 1997 (62 FR 55852). The effective date of most of the new standards contained within the final rule was April 28, 1999, but a few will not become effective until October 28, 2002.

On October 9, 1998, the Mammography Quality Standards Reauthorization Act (the MQSRA)(Pub. L. 105-248) became law. The basic purpose of the MQSRA was to extend the authorities established by the MQSA until September 30, 2002. However, the MQSRA also contained a requirement that was significantly different from the corresponding requirement in the final rule of October 28, 1997. Although this MQSRA requirement became effective on April 28, 1999, with or without the amendment of the final rule, FDA decided to amend the final rule to incorporate the change. The purpose of this amendment is to provide to the mammography facilities the convenience of being able to find all of the quality standards within a single document instead of having to consult both the final rule of October 28, 1997 and the MQSRA and to avoid confusion as to the applicable reporting requirement.

Paragraph 900.12(c)(2) of the final rule describes the requirements for communicating mammography results to the patients. As published on October 28, 1997, these requirements mandated that each mammography facility have a system to ensure that the results of each examination are communicated to the patient in a timely manner. Patients without a referring health care provider were to be sent the report of the examination (as described in section 900.12(c)(1)) directly by the mammography facility, along with a written notification or summary of the results in lay terms. It was further required by the final rule that such self-referred patients should be referred to a health care provider when clinically indicated.

In the case of patients with a referring health care provider, paragraph 900.12(c)(3) required that the health care provider receive the report of the examination. The facility's system for ensuring that results reached the patient could utilize the services of that health care provider to achieve that goal. There was no specific requirement that a summary in lay terms be provided to the patient with a referring health care provider.

The MQSRA amended the MQSA to specifically require that all patients, not just self-referred patients, receive directly from the mammography facility, a summary of the written report in terms easily understood by a lay person. As previously noted, this MQSRA requirement went into effect on April 28, 1999. FDA is amending э 900.12(c)(2) to incorporate this new requirement.

2. By Whom and for What Purpose the Information is to be Used

Information from these information collection provisions will be used by patients to manage their health care properly.

3. Consideration of Information Technology

The information may be communicated to the patient in any appropriate format.

4. Efforts to Identify Duplication and Similar Information Already Available

The information required to be sent to the patient is only available from the mammography facility.

5. Small Businesses

There are about 9800 mammography facilities performing 40 million mammograms per year. Almost all of these facilities would be considered small entities. FDA estimates that the cost of providing lay summaries per mammogram would be about $1.00. The average cost per facility would be $4,080.00

6. Consequences of Less Frequent Information Collection and Technical or Legal Obstacles.

One report is required to be given to the patient for each mammography test.

7. Consistency with the Guidelines in 5 CFR 1320.5

This regulation is consistent with principles in 5 CFR 1320.5.

8. Consultation Outside the Agency

In the **Federal Register** of June 17, 1999 FDA published a direct final rule (Tab E) and a companion proposed rule (Tab F). FDA invited interested persons to comment on the direct final rule and companion proposed rule by August 31, 1999. FDA received no comments.

9. Payments or Gifts to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Confidentiality of Information

These lay summaries will not be available to anyone other than the patient or concerned health professionals.

11. Sensitive Questions

The information collection does not include questions concerning sex, behavior, attitudes, religious beliefs, or private matters.

12. Estimates of Burden Hours and Explanation

FDA estimates that there are 9,800 facilities performing mammography in the United States. FDA also estimates that these facilities perform a total of 40 million mammography examinations in a year. In 90 percent of these cases, the notification to the patient can be established by a brief standardized letter to the patient. FDA estimates that preparing and sending this letter will take approximately 5 minutes. In the 10 per cent of the cases in which there is a finding of "Suspicious" or "Highly suggestive of malignancy", the facility is required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believes that this requirement can be met by a 5 minute call from the health professional to the patient.

FDA estimates the burden of this collection of information as follows:

Table 1--Estimated Annual Reporting Burden[1]

CFR Section	No. of Respondents	Annual Frequency per Respondent	Total Annual Responses	Hours per Response	Total Hours
900.12(c)(2)	9,800	4,080	39,984,000	5 min.	3,332,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

13. Annual Costs to Respondents

No capital or operational expenses are expected as a result of this rule.

14. Government Costs:

Costs to the government is limited to the time required to enforce the requirement as necessary. The agency has determined that no additional costs or FTE's would be required to enforce this requirement.

15. Changes in Burden

The previous burden estimate for '900.12(c)(2) was 1,000 hours. The increase in the burden hours is due to the statutory change.

16. Statistical Reporting

No publication of information for statistical use is planned.

17. Exemption for Display of Effective Date

FDA is not seeking an exemption for display of the effective date.

18. Exception to Certification Statement

There are no exceptions to the certification statement identified in Item 19 of OMB Form 83-I.

List of Attachments:

Tab A: 900.12(c)(2)

Tab B: Federal Register of December 21, 1993

Tab C: Federal Register of September 30, 1994

Tab D: Federal Register Notice; Direct Final Rule June 17, 1999

Tab E: Federal Register Notice; Companion Proposed Rule June 17, 1999